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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FOSTER, CHRISTINE E	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,199	YAMAMOTO ET AL.	
	Examiner	Art Unit	
	Christine Foster	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *1-17 and 19-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/24/01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/4/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Preliminary Amendment, filed September 24, 2001, is acknowledged and has been entered. However, the replacement paragraph does not appear to contain any changes to the paragraph in the specification as originally filed, with the exception of the apparent typographical error in the spelling of "first" in line 1.

Priority

Acknowledgement is made of the present application as a proper National Stage (371) entry of PCT Application No. PCT/JP00/01663, which was filed on March 17, 2000. Acknowledgement is also made of a claim to priority under 35 U.S.C. 119 to Japanese patent No. 11/80503, filed on March 24, 1999.

Information Disclosure Statement

Applicant's Information Disclosure Statements, filed 3/26/03, 12/1/03, 9/15/04, and 7/18/05 have been received and entered into the application.

Election/Restrictions

Claims 1-30 are currently pending. Claims 1-17 and 19-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant's election with traverse of Group II, claim 18, in the reply filed on July 18, 2005 is acknowledged. The traversal is on the ground(s) that the

Office has not applied the same standard of unity of invention as the International Preliminary Examination Authority. This is not found persuasive because the Office is not bound by the holdings of the International Preliminary Examination Authority with regard to novelty, inventive step, and industrial applicability. PCT Article 33 states that:

> The objective of the international preliminary examination is to formulate a preliminary and non-binding opinion on the questions whether the claimed inventions appears to be novel, to involve inventive step (to be non-obvious), and to be industrially applicable.

In examining the application, the examiner proceeded with unity of invention findings under 37 CFR 1.475 and found that unity of invention was lacking because the technical feature linking the inventions, which was considered to be a compound that has a relatively strong affinity with lipoproteins in a sample and a surfactant that exhibits a relatively strong action on lipoproteins in the sample in a method for quantitating cholesterol, was not novel, as detailed in the previous office action.

Applicants further traverse the requirement for restriction on the grounds that the Office has not shown that a burden exists in searching the entire application, and cites MPEP §803. Applicant is referring to the guidelines for Restriction in Applications Filed Under 35 U.S.C. 111. There is no corresponding requirement to illustrate search burden in showing lack of unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

The examiner acknowledges Applicants' request for rejoinder of non-elected claims 1-17 and 19-30 should the elected product be found allowable. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims

that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The disclosure is objected to because of the following informalities: the word "antibodies" is misspelled on p. 3, line 27. The word "first" is misspelled on p. 17, line 23 (in the preliminary amendment). The specification contains multiple references to "measuring" and "non-measuring" lipoproteins. It is suggested that the terms "measured" and "non-measured" be used as descriptors rather than the gerund forms, if this is consistent with Applicant's intended meaning.

The use of the trademark "Emulgen" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Objections

Claim 18 is objected to because of the following informalities: the claim recites "measuring" and "non-measuring" lipoproteins, which appear to be grammatically incorrect. It is suggested that the terms "measured" and "non-measured" be used as descriptors rather than the gerund forms, if this is consistent with Applicant's intended meaning.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a reagent comprising a compound having a relatively strong affinity with non-measuring lipoproteins" that are LDL and/or VLDL lipoproteins, does not reasonably provide enablement for a reagent comprising a compound having a relatively strong affinity with "non-measuring lipoproteins" that are other than LDL or VLDL lipoproteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and the invention commensurate in scope with these claims.

The claim is drawn to a reagent for use in a method for determination of cholesterol in a sample that contains a mixture of different types of cholesterol-containing lipoproteins. The reagent comprises a compound having a relatively strong affinity with "non-measuring lipoproteins," which are disclosed as those for which reaction with a cholesterol determination

reagent is not desired (p. 7, lines 14-17). Examples of such compounds or "selective affinity agents" are listed in the specification and include saponins, polyenes, cholesterol derivatives, peptides, lectins, phospholipids derivatives (p. 8, lines 11 to p. 9, line 1). Thus, the claim is broadly drawn to a genus of compounds having a relatively strong affinity with certain lipoproteins. The reagent further comprises a surfactant that exhibits a relatively strong action on other "measuring lipoproteins," which are disclosed as those lipoproteins that are to be reacted with the cholesterol determination reagent; their associated cholesterol subsequently measured (p. 7, lines 17-24).

The prior art teaches selective measurement of cholesterol in certain lipoprotein fractions in a sample containing a mixture of different lipoproteins. Sugiuchi et al. ("Direct measurement of high-density lipoprotein cholesterol in serum with polyethylene glycol-modified enzymes and sulfated alpha-cyclodextrin," *Clin Chem* **41**:717-723) teach a method for measuring HDL cholesterol using alpha-cyclodextrin and Mg^{2+}, which causes the reactivity of non-HDL cholesterols to decrease significantly, such that HDL cholesterol can be selectively measured (p. 720, left column, lines 2-5 and right column, paragraph 2 in particular).

The instant specification provides working examples of cholesterol measurement using various compound-surfactant pairs in Examples 1-7. The compounds employed in these examples are: digitonin, Chol-AECM-Pullalan, L-alpha-phosphatidylglycerol dipalmitoyl, polymyxin B, concanavalin A, and filipin. It appears that all of the Examples are applicable to methods of measuring HDL cholesterol, although this is not explicitly disclosed, as the specification does not disclose what lipoproteins constitute the "measuring" and "non-measuring" lipoproteins in these examples. In fact, cholesterol from the HDL, LDL and VLDL

fractions are all measured in the Examples. However, in light of the prior art teachings that HDL can be selectively measured by decreasing reactivity of non-HDL cholesterols, it appears that Examples 1-7 are methods of measuring HDL cholesterol, as HDL cholesterol appears to be preferentially reacted over LDL and VLDL cholesterols (for example, see Table 3 and p. 17, lines 12-15).

The specification does not disclose which lipoproteins the compounds have selective affinity for, and which lipoproteins the surfactants exhibit action on. For example, it is not disclosed that digitonin or the other compounds of the Examples has selective affinity for HDL, LDL, or VLDL. However, because the Examples have been interpreted to be directed to methods of measuring HDL cholesterol, it appears that the compounds used therein have affinity to LDL and VLDL, because the disclosure states that the compounds have affinity for non-measuring lipoproteins (p. 5, lines 2-5).

The specification does not provide examples of compounds that have selective affinities for lipoproteins other than VLDL or LDL, and there is no disclosure that the different selective affinity compounds have affinities for different lipoprotein types. Therefore, all disclosed compounds appear to have affinity to the same lipoproteins, i.e. VLDL and LDL. There are no working examples of compounds that have affinities for lipoproteins other than VLDL and LDL.

Due to the breadth of the claims, which include a large number of compounds having selective affinity for cholesterol-containing lipoproteins, the lack of direction/guidance presented in the specification regarding which type of lipoprotein the compounds have selective affinity for, the absence of disclosure of compounds that have selective affinities for lipoproteins other than LDL and VLDL, and the lack of working examples directed to a reagent for selective

measurement of cholesterol in lipoproteins other than HDL, the specification fails to teach the skilled artisan how to make and use the claimed invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "relatively strong" in claim 18 is a relative term that renders the claim indefinite. The term "relatively strong" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification states that the affinity of a selective affinity agent with a lipoprotein "must be relatively strong, but need not be absolutely strong" (p. 7, line 25 to p. 8, line 1), but does not define "relatively strong affinity" or "relatively strong action," such that the metes and bounds of the claims cannot be adequately identified.

Claim 18 is rejected as vague and indefinite for the recitation of a "relatively strong action" because this terminology does not allow for the metes and bounds of the claims to be adequately identified. The term is not defined in the specification, and it is unclear whether the action exhibited is one of surface modification or another type of action.

Claim 18 recites the limitation "the sample." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Pascal (US Patent No. 4,366,244). Pascal teaches a method for measuring cholesterol in various lipoprotein fractions including HDL and LDL/VLDL (the abstract and column 2, line 64 to column 3, line 7). The method employs lectins to selectively precipitate LDL and VLDL lipoproteins but not HDL lipoproteins (column 3, lines 8-38). Examples of lectins include concanavalin A (column 8, lines 58-60). In particular, a reagent comprising concanavalin A is taught (column 10, lines 42-60 and column 12, lines 14-17). Once the lipoproteins have been separated by lectin precipitation, each fraction may be analyzed for cholesterol (column 4, line 66 to column 5, line

3 and column 7, lines 8-11). In particular, the cholesterol of the lipoprotein fractions still in solution (i.e., HDL) is measured (column 5, lines 20-23) by enzymatic treatment and titration, employing the surfactant TritonX100 (column 6, lines 59-63 and column 12, lines 21-29 in particular). Although Pascal et al. fail to specifically recite that the surfactant exhibits a relatively strong action on measured lipoproteins, this feature would inherently be included in the method of Pascal et al. since TritonX100 is also disclosed as an example of a suitable surfactant in the instant application (see p. 10, lines 19-22).

2. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Hino et al. (US Patent No. 5,773,304, (or, alternatively, European Patent Application Publication EP 0 753 583 A1)). Hino et al. teach a method for quantitatively determining cholesterol in HDLs (the abstract) that employs a compound having selective affinity to lipoproteins other than HDLs, such that the compound forms a complex with these non-measured lipoproteins (column 2, lines 36-40 and claim 1 in particular). Examples of such compound include polyanions such as dextrin sulfate, phosphotungstic acid, and heparin; divalent metal ions; water-soluble polymers such as polyethylene glycol; and antibodies to lipoproteins other than HDLs (column 2, lines 40-47). To determine the concentration of cholesterol in HDLs, the method also employs the surfactant Triton X-100 (see Example 1, column 4, lines 2-11 in particular).

3. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Miki et al. et al. (European Patent Application Publication EP 0 754 948 A1). Miki et al. teach a method for measuring the amount of cholesterol, triglycerides, and phospholipids in specific lipoproteins in human serum in plasma, and in particular in the lipoprotein HDL (p. 2, lines 5-9 and p. 3, lines 17-18). The method employs an antibody reactive to lipoproteins other than the specific

lipoprotein measured (p. 3, lines 17-23 and 31-34). A second reagent solution is also used that preferably contains a surfactant that has the effect of promoting the measurement reaction of cholesterol in the measured lipoprotein to shorten the reaction time (p. 4, lines 27-39). Suitable surfactants include polyoxyethylene cetyl ether and polyoxyethylene alkylphenyl ether. For example, in determining cholesterol in HDL, a reagent comprising an antibody to non-measured lipoproteins (antiserum to β lipoprotein) is employed together with a reagent comprising the surfactant Triton X-100 (see Example 1).

4. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura et al. (Japanese Patent Application No. 08-134727, published as publication No. 09-313200 on December 9, 1997).

Nakamura et al. teach a method for determination of LDL cholesterol that employs a surfactant such as polyoxyethylenealkylene phenyl ether and polyoxyethylenealkylene tribenzyl phenyl ether, an enzymatic reagent for the determination of cholesterol, and a substance that exhibits a bonding affinity to VLDL stronger than the affinity to LDL (the abstract and claims 1-3 in particular). The reagents taught by Nakamura et al. anticipate the instant claim because they are used for determination of LDL cholesterol; therefore LDL constitutes the "measuring lipoprotein" and VLDL is a "non-measuring lipoprotein."

5. Claim 18 is rejected under 35 U.S.C. 102(e) as being anticipated by Nakamura et al. (US Patent No. 6,057,118, Application No. 09/147,296), or, alternatively, by the following related applications, which contain the same teachings discussed below: Nakamura et al. (US Patent No. 6,764,828 B2, which is a continuation of application No. 09/147,296, which was filed as application No. PCT/JP97/01232 on April 10, 1997); Nakamura et al. (US Patent No. 6,333,166

B1, which is also a continuation of application No. 09/147,296); Nakamura et al. (US Patent Application Publication 2004/0219623, corresponding to application No. 10/859,999, which is a continuation of application No. 09/971,673, which is a continuation of 09/510,170, which is itself a continuation of 09/147/296).

Nakamura et al. teach a reagent for quantitative determination of LDL cholesterol that comprises a surfactant, a substance having a stronger bonding affinity to non-measuring lipoproteins (i.e., VLDL) as compared to the measuring lipoproteins (LDL), and a cholesterol determination reagent ("cholesterol-assaying enzyme reagent") (see column 2, line 50 to column 3, line 12). The substance can be polyanions such as phosphotungstic acid, dextran sulfate, and heparin; or substances forming a divalent metal salt (column 3, lines 37-57). The surfactants taught by Nakamura et al. include polyoxyethylenealkylene phenyl ethers and polyoxyethylenealkylene tribenzylphenyl ethers (column 3, lines 37-55), which are also disclosed as examples of suitable surfactants according to the instant invention (p. 10, lines 14-16) and would therefore inherently exhibit a relatively strong action on measuring lipoproteins.

The applied reference(s) has common inventors and assignment with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Double Patenting

6. Claim 18 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 6 and 8-13 of U.S. Patent No. 6,764,828, or, alternatively, over claims 2-4 and 9 of U.S. Patent No. 6,333,166, or, alternatively, over claims 2-4 and 9 of U.S. Patent No. 6,057,118.

U.S. Patents '828, '166, and '118 are as discussed above. US Patent '118 corresponds to application No. 09/147,296. US Patent '828 is a continuation of application No. 09/510,170, which is a continuation of application No. 09/147,296. U.S. Patent No.'166 is a continuation of application No. 09/147,296. The teachings discussed below may be found in the disclosures of each patent.

Although the conflicting claims are not identical, they are not patentably distinct from each other because '828 recites a reagent for quantitative determination of low density lipoprotein (LDL) cholesterol that comprises a surfactant (polyoxyethylenealkene phenyl ethers or polyoxyethylenealkene tribenzylphenyl ethers), a cholesterol determination reagent "cholesterol-assaying enzyme reagent," and substance having a stronger bonding affinity to very low density lipoproteins (VLDL) as compared to LDL. Dependent claims 8-13 add limitations regarding the type or amount of the substance, which can be polyanions such as phosphotungstic acid, dextran sulfate, and heparin; or substances forming a divalent metal salt. Dependent claim 6 further limits the cholesterol determination reagent as comprising cholesterol esterase and cholesterol oxidase, which are also employed in the instant application, for example at p. 15, lines 4-5.

Correspondingly, '166 and '118 recite a method for quantitative determination of LDL using the reagent discussed above, wherein the substance may be a polyanion or a divalent metal salt. Dependent claims add further limitations to the identity of the substance or the to the identity of the cholesterol determination reagent.

The substance recited in '828, '118 and '166 has selective affinity to VLDL lipoprotein, while the instant claim is directed more broadly to a compound that has selective affinity to any non-measured lipoprotein. However, it would have been obvious to one of ordinary skill in the art to employ the reagent of '828 or, correspondingly, the methods of '166 or '118 for quantitative determination of LDL (as recited in lines 1-2 of claim 1 in both patents) and to recognize that LDL constitutes "measuring lipoprotein" and that VLDL constitutes "non-measuring lipoproteins."

7. Claim 18 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-3 and 5 of copending Application No. 10/859999, filed 6/4/04.

The conflicting claims are drawn to a method and a kit for quantitative determination of LDL cholesterol comprising a surfactant selected from polyoxyethylenealkylene phenyl ethers and polyoxyethylenealkylene tribenzylphenyl ethers and further comprising a substance that exhibits stronger bonding affinity to VLDL (non-measured lipoprotein) than to LDL (measured lipoprotein). One skilled in the art would recognize when using the kit of 10/859999 for measurement of LDL, the LDL lipoproteins constitute "measuring lipoproteins" and VLDL lipoproteins constitutes "non-measuring lipoproteins." It would have been further obvious to one of ordinary skill in the art to employ the method and kit in conjunction with a cholesterol

determination reagent because the method of claims 2-3 recite the step of determining cholesterol and reagents for such purpose are well known in the art.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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